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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
· 10/527,771	03/11/2005	Edwin Claerebout	I-2002.015 US	5406
31846 75	590 11/15/2006	•	EXAMINER	
INTERVET INC.			GANGLE, BRIAN J	
PATENT DEPA	ARTMENT			
PO BOX 318			ART UNIT	PAPER NUMBER
MILLSBORO, DE 19966-0318			1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)		
	10/527,771	CLAEREBOUT ET AL.		
Office Action Summary	Examiner	Art Unit		
	Brian J. Gangle	1645		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. sely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
1) Responsive to communication(s) filed on 24 Au  2a) This action is <b>FINAL</b> .  2b) This  3) Since this application is in condition for allowant closed in accordance with the practice under E.	action is non-final. ace except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) 30-49 is/are pending in the application 4a) Of the above claim(s) 30-33,41-43 and 45-4 5) ☐ Claim(s) is/are allowed. 6) ☒ Claim(s) 34-36,40 and 44 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☒ The specification is objected to by the Examine	19 is/are withdrawn from consider	ation		
10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the confidence of Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Expression of the confidence of the confide	drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119		•		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate		

## **DETAILED ACTION**

Applicant's amendment is acknowledged. Claims 30-49 are pending. Claims 30-33, 37-39, 41-43, and 45-49 are withdrawn. Claims 34-36, 40, and 44 are currently under examination.

# Objections Withdrawn

The objection to the specification because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn in light of the amendment thereto.

The objection to claim 35 because it is dependent on a non-elected claim is withdrawn in light of the amendment thereto.

## **Objections Maintained**

The objection to the specification because of improper use of trademarks is maintained. Although applicant has amended the specification to include the term "non-ionic detergent," this is not an appropriate generic description for Triton X-100. It is suggested that applicant consult the MSDS sheet for Triton X-100 to determine the appropriate chemical name. Further, applicant should review the specification to correct any other use of trademarks. For example, the trademark Trizol can be found on page 26.

## Claim Rejections Withdrawn

The rejection of claims 36, 40 and 44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of the amendments thereto.

The rejection of claim 36 as being vague and indefinite because of the phrase "a vaccine for combating *Ostertagia ostertagi* infection" is withdrawn in light of the amendments thereto.

The rejection of claim 36 as being vague and indefinite because of the phrase "a vaccine... comprising at least one *Ostertagia ostertagi* protein or an immunogenic fragment of said protein according to claim 34" is withdrawn in light of the amendments thereto.

The rejection of claim 44 as being vague and indefinite because of the phrase "a diagnostic kit comprising a suitable detection means and a protein or immunogenic fragment thereof according to claim 34" is withdrawn in light of the amendments thereto.

The rejection of claims 36 and 40 under 35 U.S.C. 102(a) as being anticipated by Claerebout et al. (Novel Approaches Meeting III, Moredun Research Institute, 7/2002, IDS filed 2/10/2006) is withdrawn in light of the amendments thereto.

The rejection of claims 36 and 40 under 35 U.S.C. 102(b) as being anticipated by Silverman (US Patent 3,395,218, 1968) is withdrawn in light of the amendments thereto.

The rejection of claim 44 under 35 U.S.C. 102(b) as being anticipated by Pastan *et al.* (US Patent 6,232,086, May, 2001) is withdrawn in light of the amendments thereto.

# Claim Rejections Maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 34-36, 40, and 44 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is maintained for the reasons set forth in the previous office action.

Applicant argues: that the amendment of said claims renders the rejection moot.

Applicant's arguments have been fully considered and deemed non-persuasive. Applicant has amended the claims to read on a protein that has a sequence as depicted in SEQ ID NO:10, and a protein encoded by a nucleic acid sequence as depicted in SEQ ID NO:9. The phrase "a sequence" merely requires that there be any sequence in common. Since only two amino acids or nucleic acids are required to make a sequence, the claims encompass an even

larger genus than was claimed previously. It is suggested that applicant amend the claims to read on the protein that has *the* sequence of SEQ ID NO:10 or the protein that is encoded by *the* nucleic acid sequence of SEQ ID NO:9.

As stated previously, the specification discloses SEQ ID NO: 10 that corresponds to a 30 kD *Ostertagia ostertagi* protein and SEQ ID NO: 9 that corresponds to a nucleic acid sequence that encodes said 30 kD *Ostertagia ostertagi* protein. SEQ ID NO: 9 and 10 meet the written description provision of 35 USC 112, first paragraph. However, the aforementioned claims encompass sequences that have any sequence depicted in SEQ ID NO:9 and 10. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 9 and 10, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid and/or protein itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to

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recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Therefore, only SEQ ID NO: 9 and 10, but not the full breadth of the claims, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115).

The rejection of claims 34-36, 40, and 44 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated and purified 30 kD *Ostertagia ostertagi* protein having the sequence set forth in SEQ ID NO: 10, and for an *Ostertagia ostertagi* protein encoded by the nucleic acid sequence set forth in SEQ ID NO: 9, does not reasonably provide enablement for the myriads of other polypeptides species claimed, is maintained for the reasons set forth in the previous office action.

Applicant argues: that the amendment of said claims renders the rejection moot.

Applicant's arguments have been fully considered and deemed non-persuasive.

Applicant has amended the claims to read on a protein that has a sequence as depicted in SEQ ID NO:10, and a protein encoded by a nucleic acid sequence as depicted in SEQ ID NO:9. The phrase "a sequence" merely requires that there be any sequence in common. Since only two

amino acids or nucleic acids are required to make a sequence, the claims encompass an even larger genus than was previously claimed. It is suggested that applicant amend the claims to read on the protein that has *the* sequence of SEQ ID NO:10 or the protein that is encoded by *the* nucleic acid sequence of SEQ ID NO:9.

As stated previously, the specification is enabling only for claims limited to proteins represented by SEQ ID NO: 10 and for proteins encoded by the nucleic acid sequence represented by SEQ ID NO: 9 because the specification does not reasonably provide enablement for polypeptides having a sequence depicted in SEQ ID NO: 10 or to proteins encoded by nucleic acids having a sequence depicted in SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The claims are drawn to Ostertagia ostertagi proteins with any amino acid sequence recited in SEQ ID NO: 10 and to Ostertagia ostertagi proteins encoded by a nucleic acid molecule with any nucleic acid sequence recited in SEQ ID NO: 9. Said proteins have no claimed biochemical, immunological or physiological function. Protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique threedimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess et al (J. of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine reside at position 118 of

acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar et al. (Molecular and Cellular Biology, 1988, 8:1247-1252) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. Clearly, proteins with up to 10% dissimilarity to the polypeptides of SEQ ID NO: 10 (or up to 15% dissimilarity to SEQ ID NO: 9) that maintained the characteristics of the polypeptides encoded by SEQ ID NO: 10 could not be predicted. Additionally, Bork (Genome Research, 2000,10:398-400) clearly teaches the pitfalls associated with comparative sequence analysis for predicting protein function because of the known error margins for high-throughput computational methods. Bork specifically teaches that computational sequence analysis is far from perfect, despite the fact that sequencing itself is highly automated and accurate (p. 398, column 1). One of the reasons for the inaccuracy is that the quality of data in public sequence databases is still insufficient. This is particularly true for data on protein function. Protein function is context dependent, and both molecular and cellular aspects have to be considered (p. 398, column 2). Conclusions from the comparison analysis are often stretched with regard to protein products (p. 398, column 3). Further, although gene annotation via sequence database searches is already a routine job, even here the error rate is considerable (p. 399, column 2). Most features predicted with an accuracy of greater than 70% are of structural nature and, at best, only indirectly imply a certain functionality (see legend for table 1, page 399). As more sequences are added and as errors accumulate and propagate it becomes more difficult to infer correct function from the many possibilities revealed by database search (p. 399, paragraph bridging columns 2 and 3). The reference finally cautions that although the current methods seem to capture important features and explain general trends, 30% of those features are missing or predicted wrongly. This has to be kept in mind when processing the results further (p. 400, paragraph bridging cols 1 and 2). Clearly, given not only the teachings of Bowie et al., Lazar et al. and Burgess et al. but also the limitations and pitfalls of using computational sequence analysis and the unknown effects of alternative splicing, post translational modification and cellular context on protein function as taught by Bork, the claimed

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proteins could not be predicted based on sequence identity to SEQ ID NO: 10 or on sequence identity with the encoding nucleic acid (SEQ ID NO: 9). Further, even if a given polypeptide possesses all the structural limitations of the claimed invention, neither the specification nor any art of record teaches what that polypeptide is, what it does, does not teach a relationship to any specific disease or establish any involvement of the polypeptide in the etiology of any specific disease or teach which fragments might be active or which derivatives would function as claimed in a pharmaceutical composition. Clearly, it could not be predicted that polynucleotide, or a variant, that encodes a protein that shares only partial homology with a disclosed protein or that a protein that is encoded by a "variant" of a given SEQ ID NO: will function in a given manner. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus of proteins. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

The rejection of claims 36 and 40 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained for the reasons set forth in the previous office action.

Applicant has provided no arguments regarding this rejection and has asked that the rejection held in abeyance.

Applicant is reminded that rejections are not held in abeyance.

As stated previously, the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to vaccine compositions comprising *Ostertagia ostertagi* proteins with any amino acid sequence recited in SEQ ID NO: 10 and comprising *Ostertagia ostertagi* proteins encoded by a nucleic acid molecule with any nucleic acid sequence recited in SEQ ID NO: 9.

The specification teaches that rabbits injected with a protein having the sequence set forth in SEQ ID NO: 10 produced antibodies that were able to bind to SEQ ID NO: 10. However, the specification is devoid of any teaching that said proteins provide an effective vaccine against any

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disease. The rejected claims are drawn to prophylactic compositions comprising parasitic proteins against " Ostertagia ostertagi infection" wherein said vaccines comprise Ostertagia ostertagi proteins or fragments with 90% homology to the amino acid sequence recited in SEQ ID NO: 10 or Ostertagia ostertagi proteins encoded by a nucleic acid molecule with 85% homology to the nucleic acid sequence recited in SEQ ID NO: 9. To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The skilled artisan would clearly realize the critical deficiency of this specification with respect to vaccines. There is absolutely no demonstration of protective immunity upon administration in any animal model of disease by the proteins described in the specification. Therefore it is not clear that the described proteins are capable of generating an active immune response such as an antibody response that protects the animal against any type of disease. Although many investigators have tried to develop vaccines based on specific antigens, it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection (Chandrashekar et al., US Patent 6,248,329, col. 1, lines 35-41). It is well recognized in the vaccine art, that it is unclear whether an antigen derive from a pathogen will elicit protective immunity. Ellis (Chapter 29 of Vaccines, Plistkin, et al. (eds) WB Saunders, Philadelphia, 1998, especially p. 571, paragraph 2) exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen." The specification fails to teach that any of the proteins disclosed can produce a protective response in the host, as is requisite of a vaccine composition. In view of the lack of support in the art and specification for an effective vaccine comprising the claimed proteins, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine as claimed; therefore the claims are not enabled.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 34-36, and 40 under 35 U.S.C. 102(b), as being anticipated by Coyne (US Patent 6,017,757, 1/25/2000), is maintained for the reasons set forth in the previous office action.

Applicant argues: that the proteins disclosed by Coyne are not the same as those of the instant application. Applicant argues that the proteins disclosed by Coyne have aminopeptidase M activity, and that all aminopeptidase M enzymes have a consensus sequence that is absent in the instantly claimed protein; therefore, the proteins disclosed by Coyne cannot be the same as the instantly claimed protein.

Applicant's arguments have been fully considered and deemed non-persuasive.

The claims only require that the protein be 30kd and have a sequence depicted in SEQ ID NO:10, or be encoded by a nucleic acid that has a sequence depicted in SEQ ID NO:9. The claims do not require the protein to actually have the entire sequence of SEQ ID NO:10, or to be encoded by a nucleic acid with the entire sequence of SEQ ID NO:9. Only 2 consecutive amino acids or nucleic acids in common are required to meet the limitations of the claims. Therefore, if the proteins disclosed by Coyne do have the aminopeptidase M consensus sequence, and the protein with the amino acid sequence of SEQ ID NO:10 does not, this does not mean that the proteins of Coyne do not meet the limitations of the claims.

As outlined previously, the instant claims are drawn to an isolated and purified 30 kD Ostertagia ostertagi protein, wherein said protein has a sequence as depicted in SEQ ID NO: 10 (claim 34); an Ostertagia ostertagi protein, wherein said protein is encoded by a nucleic acid sequence as depicted in SEQ ID NO: 9 (claim 35); a vaccine for combating Ostertagia ostertagi infection, comprising: at least one Ostertagia ostertagi protein according to claim 34 and a pharmaceutically acceptable carrier (claim 36); and the vaccine according to claim 36, further comprising an adjuvant (claim 40).

Coyne discloses an *Ostertagia ostertagi* protein with an approximate molecular weight of 29-33 kD (see column 25, lines 14-17). Due to the similarity in molecular weight between the protein disclosed by Coyne and the protein of the instant invention it is deemed, in the absence of evidence to the contrary, that the two proteins are the same. As the amino acid sequence of a

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protein is an inherent property of a protein, Coyne anticipates the claimed invention since the identification of a new characteristic of a known product does not make that product patentable (see MPEP 2112 R-3). The term "vaccine" is an intended use and is given no patentable weight, therefore the claims are drawn to a composition comprising an isolated and purified 30 kD *Ostertagia ostertagi* protein, wherein said protein has a sequence as depicted in SEQ ID NO: 10; an *Ostertagia ostertagi* protein, wherein said protein is encoded by a nucleic acid sequence as depicted in SEQ ID NO: 9. Moreover, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

#### Conclusion

No claim is allowed.

SEQ ID NO:9 and 10 are free of the art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle AU 1645

> ROBERT A. ZEMAN PRIMARY EXAMINER